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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,624	08/15/2005	Christopher Anthony Morris	4501-1015	7843

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
03/10/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/519,624	MORRIS ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,10 and 17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-6,9 and 10* is/are allowed.

6)☒ Claim(s) *17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/10 has been entered.

2. The rejection of claims 1-6, 9, and 10 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is WITHDRAWN because the claims clearly set forth a step of testing genetic material.

3. The rejections of claims 1, 2, 3, 4, 5, 6, 9, and 10 under 112 1st paragraph are overcome by amendment to the claims. These claims are allowed. The prior art does not teach or suggest the identifying step set forth in part (c) of claim 1.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 17-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a rejection for new matter.

Claim 17 is newly amended. Part (b) requires selecting a first number of cows with the proline genotype and a second number of cows with a histidine genotype "that will likely alter the level of saturated fatty acids and level of unsaturated fatty acids relative to the milk obtained from the group of two or more cows." There is no basis in the specification for selecting different numbers of cows with certain genotypes for the effect of "likely" altering the composition of the obtained milk relative to a whole group's milk composition. Applicants point to particular portions of the specification to provide support for "the amendment to the claims," but none of these portions of the specification discuss proportions, nor do they disclose determining milk levels based on proportions.

Notes:

On page 11 of the response filed 1/29/10 applicant points to page 3, lines 1-17 as providing support for the amended claim. This section teaches testing the genotype to determine which cows of a herd produce milk containing a β-casein having a proline residue at position 67, and selecting those cows. This section makes no mention of selecting some cows that have the histidine genotype at position 67. Applicant also points to lines 20-23 of page 4 which teaches a "method of altering the proportions of saturated fatty acids and unsaturated fatty acids in a food by adding to the food an amount of β-casein having a proline at position 67." This section makes no mention of selecting some cows that have the histidine genotype at position 67. The

specification never discusses screening for the genotype and then milking herds of cows that are "mixed" for the genotypes.

Applicant refers to the specification, page 6, lines 1-10. This portion teaches A1 milk has a higher percentage of saturated fatty acids and a lower percentage of unsaturated fatty acids compared to A2 milk, and thus, milk that is substantially free of β-casein A1 will produce milk fat that has lower levels of saturated fatty acids and medium chain fatty acids. There is no mention of different numbers of cows that have particular genotypes.

Applicant refers to the specification, page 8, lines 1-12. This portion teaches to use the test for β-casein genotype to select animals to breed herds for milking, preferably forming herds where A1 β-casein is absent from the herd, or where only A2 milk is present. There is no discussion here about altering the levels of the fatty acid content of milk based on using different numbers of cows having particular genotypes present.

The examiner was not able to identify explicit or implicit teaching of using selected numbers of cows with different genotypes to alter the level of unsaturated fatty acids in milk obtainable from the cows.

6. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Elliott et al. (WO 96/14577).

Elliott et al. teach a method which comprises steps of (a) testing genetic material of individual cows of the herd for the presence of DNA encoding β-casein having a histidine at position 67 or by testing milk produced by individual cows of the herd for the presence of β-casein having a proline at position 67; (b) selecting cows that produce milk containing a β-casein

having a proline residue at position 67; and (c) milking the selected cows. Namely, referring to page 2 of Elliott, they teach a method which comprises testing milk from identified cows for the presence of variants of β-casein, selecting those cows whose milk contains the preferable A2 variant of β-casein, milking those cows and recovering the milk (lines 21-26). Elliott et al. also teach that the cows or bulls can be genotyped directly using appropriate probes and polymerase chain reaction technology; this technology inherently tests genetic material of individual cows (p. 4, lines 23-24). Regarding step (b), Further, Elliott et al. teach that the milk should not contain the variant A1 (line 29), and are thus selecting cows "based on" the presence of a DNA encoding β-casein having a proline residue at position 67. It is an inherent feature of these cows that they are "more likely to have a lower percentage of saturated fatty acids and a higher percentage of unsaturated fatty acids." The A2 variant inherently has a proline residue at position 67, and the A1 variant inherently has a histidine at position 67. Elliott et al. are silent as to the intended use in part (c) of the claim of obtaining milk with a particular fatty acid composition. The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the prior art would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method disclosed in the prior art reference. Therefore, the practice of the method taught by Elliott et al. inherently meets the limitations of the claimed method.

7. Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by McLachlan (US 6,570,060).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

McLachlan teaches a method which comprises steps of (a) testin which cows of a herd produce milk containing β-casein having a proline at position 67 by testing DNA or RNA (i.e. genetic material) from cells containing DNA or RNA obtained from one or more lactating bovines for the presence of DNA or RNA encoding β-casein A1 or A2 ; (b) selecting cows that produce milk containing a β-casein having a proline residue at position 67 (i.e. β-casein A2); and (c) milking the selected cows (Col. 3-4 of McLachlan). The A2 variant inherently has a proline residue at position 67, and the A1 variant inherently has a histidine at position 67. Therefore, the practice of the method taught by McLachlan meets the limitations of the claimed invention.

Double Patenting

8. Claim 25 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,570,060. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the issued patent anticipate the instantly claimed invention. The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the issued patent would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by

the practice of the method disclosed in the issued patent, and the claims of the issued patent anticipate the instantly claimed invention.

9. Claim 25 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. US 7,094,949. Although the conflicting claims are not identical, they are not patentably distinct from each other because anticipate the instantly claimed invention. The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the issued patent would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method disclosed in the issued patent, and the claims of the issued patent anticipate the instantly claimed invention.

10. Claim 25 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,157,616. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious in view of the claims of the issued patent. The issued patent teaches selecting cows by determining the genotype of the cows and selecting those which produce milk which contains a β-casein variant with a proline at position 67 and does not contain variants with a histidine at amino acid 67, and further teaches that the genotyping is by using a probe and PCR. The claims do not expressly teach milking the cows to obtain the milk, but this would have been prima facie obvious to one of ordinary skill in the art, upon having practiced a method of selecting cows for their milk composition, in particular since the claims teach that the milk is not diabetogenic. The fatty acid composition of milk obtained from a cow that has the β-casein

A2/A2 genotype obtained using the method disclosed in the issued patent would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method disclosed in the issued patent, and the claims of the issued patent anticipate the instantly claimed invention.

11. Claim 25 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 7,629,119. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate each of the instant claims, see in particular claim 13. The fatty acid composition of milk obtained from a cow that has the β-casein A2/A2 genotype obtained using the method disclosed in the copending claims would inherently have the features set forth in the instantly claimed invention, as it is the same milk. The intended use set forth in the claim is thus inherently met by the practice of the method claimed in the copending application, and the claims of the copending application anticipate the instantly claimed invention.

Response to Remarks

The remarks, insofar as they are relevant to the rejections to the amended claims are addressed in the rejections themselves.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The

examiner can normally be reached on Monday or Tuesday, from 9:00 AM until 4:30 PM, and Wednesday mornings from 8:00 AM until noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached by calling (571) 272-0763.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-

9199.

/Juliet C. Switzer/
Primary Examiner
Art Unit 1634

March 8, 2010